

arms is open at the free end portion thereof (*See, e.g.*, Specification at page 9, lines 11-12). Claim 17 has been amended to recite that the identification means includes a gender-identifying color associated with a portion of the clamp to facilitate identification of the gender of the baby (*See, e.g.*, Specification at page 10, lines 7-14). Claims 18 and 20 have been amended without modification of their scope to correct technical changes based on the other amendments discussed herein. Claim 19 has been amended to recite that the entire clamp comprises one or more shades of the color and claim 22 has been amended to recite that a portion is the gender-identifying color and a portion is a neutral color (*Id.*). Claim 21 has been amended to recite that the identification means further comprises security apparatus or other specific features to inhibit or prevent unauthorized removal of the baby (*See, e.g.*, Specification at page 11, lines 3-15). Claim 23 has been amended to clarify that the gender identification based on clamp color occurs visually (*See, e.g.*, Specification at page 10, line 17). Claim 24 has been amended to clarify that the identification means is analyzed to determine the mother of the newborn so as to minimize the chance of misidentification of the baby or the mother thereof (*See, e.g.*, Specification at page 11, lines 3-7). Claim 25 has been amended to more clearly recite the final step and to depend from claim 21 (*Id.*). No new matter has been added by way of these amendments, such that their entry at this time is warranted. A marked up version of the amended specification and claims are attached as Appendices A and B, respectively. A clean set of the pending claims is attached hereto as Appendix C.

Claims 1-8, 11-13, 16-17, and 21-25 14 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,006,830 to Merritt (“Merritt”) on pages 2-3 of the Office Action. The Office Action states that Merritt has a grasping portion (21,22) in FIG. 1, a channel (23,24) that extends along the length of at least one arm to facilitate the escape of fluid when the clamp is closed, and various other recited features of the clamp. Merritt is also stated to teach identification means (30) for identifying the baby (Col. 4, lines 10-40).

Merritt does not disclose or even suggest a separate and distinct grasping portion from the conventional flared end of a clamp to facilitate clamp use, as now recited in claim 1. The grasping portion of claim 1 has been amended simply to clarify that it is distinct from the flared end that is present in most conventional umbilical cord clamps. Also, claim 8 now recites a particular location for the grasping portion, which is distinct from the flared end portion. The conventional flared ends are disclosed solely on the ends of the clamps (Merritt, FIGS. 1-3). Thus, Merritt fails to disclose a separate grasping portion in addition to the flared

ends it does disclose, as well as a grasping portion disposed in a different location than the end of the arms, as presently recited in one or more of claims 1-11.

With respect to claims 12-16, Merritt does not disclose or even suggest that the channel in each arm is open at the end. Merritt simply teaches that a groove is present in a portion of each arm along a portion of the length of each arm *to prevent the clamp from slipping off the umbilical cord*. The Office Action refers to feature 23,24, which is clearly a groove in FIG. 6 and discussed at Col. 3, lines 54-63. FIG. 6 of Merritt is merely a cross-section that does not teach anything regarding the open or closed nature of the ends of the channels, but it is clear from the dashed lines in FIG. 1 that this groove does not extend along the full length of each arm. In fact, this explicitly teaches that the groove in each arm terminates so that it is closed at each end of the arm. On the contrary, claim 12 of the present invention now more clearly recites that the channel is open at the free end to facilitate the escape of fluid therefrom when the clamp is closed according to the present invention. Since Merritt fails to disclose an open-ended channel at the free end of an arm, nor would it need to for its desired purpose of grasping the cord better, it cannot anticipate the invention of claims 12-16. Moreover, Merritt fails to disclose that the channel is open to a lateral groove disposed between the teeth and the tongue, as recited by claim 16. For these reasons, Merritt does not anticipate claims 12-16.

Regarding claims 17-25, Merritt discloses an identification system to deter the unauthorized removal of a newborn from a defined area. As such, it discloses a clamp that contains particular types of identification marks including a serial code, bar code, color code, or letter combination, each of which has a different distinctive mark thereon (Col. 4, lines 10-24). Merritt fails to disclose the inclusion of a color, including shades thereof, to provide identification means comprising a gender-identifying color to facilitate identification of the gender of a newborn baby, as presently recited. At best, it discloses a *color code* to prevent unauthorized removal of a newborn from a pre-defined area. Thus, Merritt requires a color code, which is presumably at least a pattern of multiple colors, to provide identification for its stated purpose of preventing unauthorized removal. Since Merritt does not teach a gender-identifying color to facilitate identification of the baby's gender, as presently recited, it cannot anticipate amended claim 17.

Moreover, Merritt fails to disclose that a portion of the clamp is blue and the remainder is a neutral color for a boy and a portion of the clamp is pink and the remainder is a neutral color for a girl. Not only does Merritt fail to disclose or even suggest using color to identify gender, but it clearly fails to teach that a portion of the clamp is blue for a boy and pink for a girl. Further, Merritt does not teach methods of identifying gender of a newborn
291320.1

baby at all, particularly in a visual fashion based on color, as presently recited. Also, Merritt does not teach methods of identifying a newborn and mother to minimize the risk of misidentification, *i.e.*, when children and their mothers are accidentally swapped. In sum, since Merritt fails to teach each and every feature presently recited, it cannot anticipate the claimed invention. Also, since Merritt is directed to a completely different invention--that of preventing unauthorized removal of a baby from a pre-defined area--it does not even suggest the claimed features presently recited. Thus, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Claims 9, 11, 14-15, and 18-20 were also rejected under 35 U.S.C. § 103(a) as being obvious over Merritt on pages 4-5 of the Office Action. The Office Action states that the criticality of the various dimensions such as claims 9, 11, and 14-15 regarding the grasping portion and the channel are simply routine experimentation that would have been obvious to those of ordinary skill in the art. The Office Action also concedes that Merritt teaches color code but did not teach blue for boys and pink for girls, but that such an association is well known in the baby delivery field such that it would have been obvious. As support, the Examiner points to the use of colored bonnets for boy and girl newborns.

Initially, Applicant notes that this rejection involves only dependent claims. Each claim rejected here depends from one of independent claims 1, 12, or 17, and as such is patentable as previously discussed. In addition, Merritt is directed solely to deterring unauthorized removal of newborns from a defined area. Merritt does not teach a grasping portion distinct from the flared portion at the end the arm, such that the location recited in claim 9 and the size recited in claim 11 cannot be rendered obvious. As for claims 14-15, which are dependent from claim 12, Merritt completely fails to suggest the removal of fluids, and its structure would not inherently do so (See FIG. 1, dashed lines). Also, the size and shape of the channel, as recited in claims 14-15, are each important to the claimed invention whereby the channel facilitates removal of fluids from the clamp when it is closed. Merritt only teaches that a closed channel can be included to help grip the umbilical cord when the clamp is closed. Thus, no motivation existed based on the teaching of Merritt for one of ordinary skill in the art to modify the presently recited channel.

Merritt also *teaches away* from claims 18. Although Merritt discloses a color code as an identification means, it is for the purpose of preventing unauthorized removal of newborns. On the contrary, the present invention recites gender identification in claim 18, such that Merritt teaches away from claim 18. Merritt also discloses that every clamp should have a different distinctive identification mark thereon, however, the recited pink and blue are not a sufficient universe of colors to create a "color code" or to uniquely and distinctly

identify every newborn in a given hospital or health care facility. Claim 18 recites that the gender-identifying color includes pink or blue, and such a simple color scheme is simply not even suggested by Merritt since it is directed to unauthorized removal of babies.

Also, no motivation existed for one of ordinary skill in the art to have made colored clamps to identify gender, or to modify clamps in this way based on traditional use of clothing to identify gender. The Office Action refers to blue and pink bonnets, however, the Examiner's attention is specifically directed to the surprising and unexpected advantages of the claimed invention relative to such conventional gender identification (Specification at page 10, lines 17-28). Conventional colored clothing has a tendency to fall off babies as any parent will know, and the wrong colored bonnet could easily be applied to a fully-clothed baby (*e.g.*, by an overworked, exhausted health care provider). The present invention, however, elegantly solves this problem by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later times when clothes are worn. The clamp of the invention does not typically fall off, either, and remains with the diapered-newborn baby until the cord falls off, which is generally after the baby departs from the hospital or other pre-defined area. The simple fact is that millions of babies are delivered annually, and to the Applicant's knowledge no one has ever achieved such a simple, elegant solution to the problem of gender misidentification of newborn babies. In fact, it should be clear common sense that there is a long-felt need in the obstetric art for the improved gender-identifying clamp provided by the claimed invention. For these and other reasons, the rejection under 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn, particularly since no *prima facie* case of obviousness has been stated on the record.

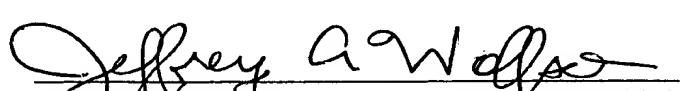
Accordingly, Applicants now believe all claims are in condition for allowance. Should the Examiner not agree with this position, a telephone or personal interview is requested to resolve any remaining issues and expedite allowance of this application.

No fee is believed to be due for this response. Should any fees be required, however, please charge such fees to Winston & Strawn Deposit Account No. 501-814.

Respectfully submitted,

1/24/03

Date



Jeffrey A. Wolfson (Reg. No. 42,234)
For: Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN
Customer Number: 28765
(202) 371-5770